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M11481X

BIO-DESIGN INC

OPERATING INSTRUCTIONS

MP MASTER
MA30353

MICROGUARD®

MODEL MG-3

INSTRUCTION MANUAL

MICROGUARD® SAFETY TESTER

Model MG-3

For use with MICROGUARD serial numbers

31001 and higher

Printed in U.S.A.
July 1974

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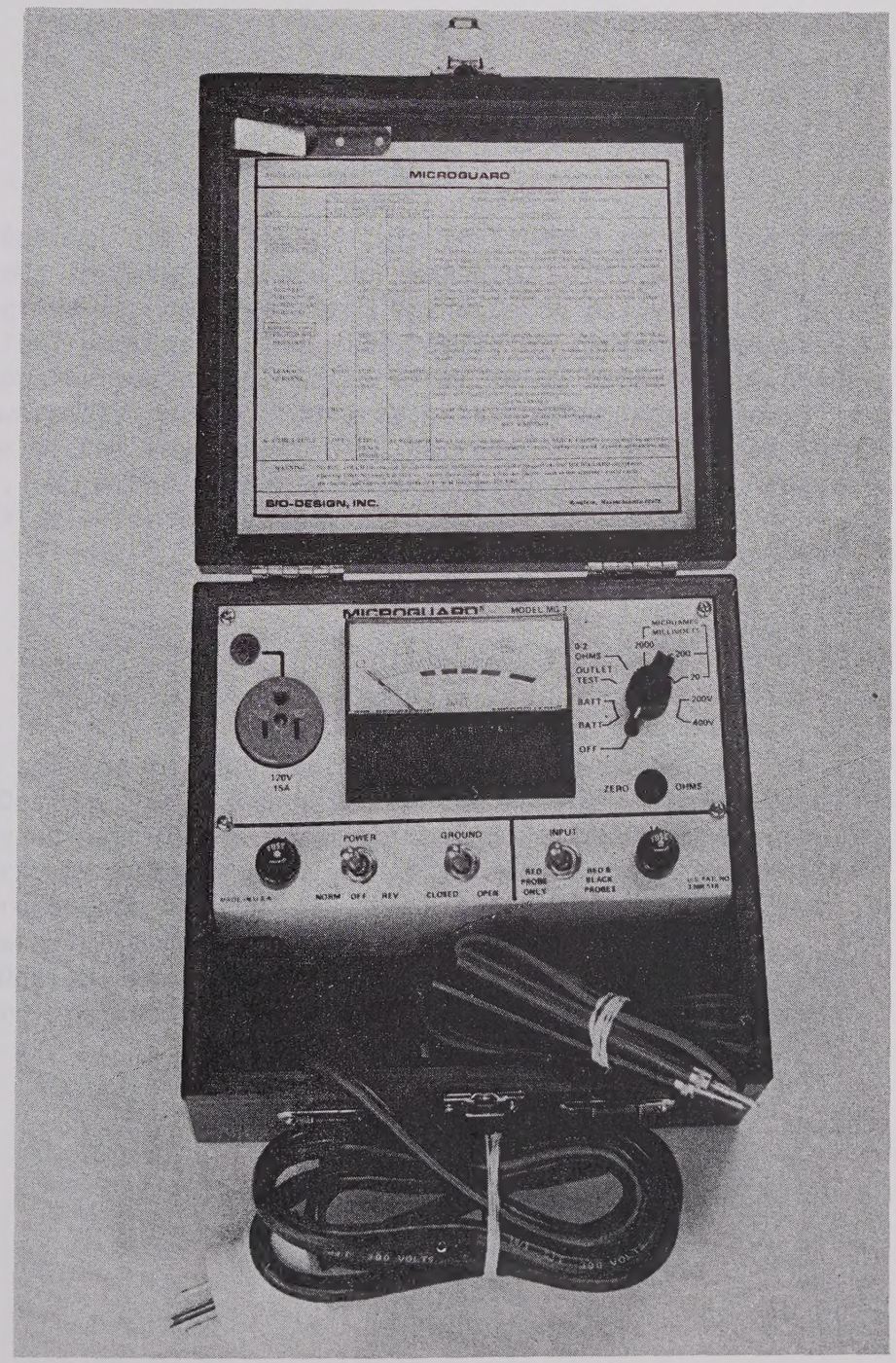

MICROGUARD
BIO-DESIGN, INC.
MICROGUARD
MODEL MG-7
0-2 OHMS
OUTLET TEST
BATT
BATT
OFF
2000
200
20
200V
400V
ZERO
OHMS
120V
15A
POWER
NORM OFF REV
GROUND
CLOSED OPEN
INPUT
RED PROBE ONLY
RED & BLACK PROBES

WARRANTY

Bio-Design, Inc. warrants this instrument to be free from defects in materials and workmanship. This warranty is effective for one year from the date of delivery to the original purchaser. We will repair or replace products, except for batteries, which prove to be defective within the warranty period. Defects arising from misuse or abuse of the instrument will be repaired or replaced at cost. No other warranty is expressed or implied. We are not liable for consequential damages.

SERVICE

When service is required, write, wire or phone Bio-Design, Inc. Depending on the nature of the defect, every effort will be made to ship a replacement part or instrument immediately. If it is necessary to return the instrument to the factory, pack carefully and securely, preferably in the original carton, and return it to Bio-Design, Inc., with shipping charges prepaid. Do not return products to Bio-Design, Inc. without prior consent.

WARNING

DO NOT TOUCH the chassis or exposed metal surfaces of an appliance plugged into the MICROGUARD receptacle when the GROUND switch is OPEN. Under these conditions a line-to-chassis fault in the appliance could cause its chassis and exposed metal surfaces to be at line voltage, 120 VAC.

CONTENTS

I. GENERAL INFORMATION

1.0 Introduction
2.0 Specifications
3.0 Special Features
4.0 Accessories

II. OPERATING INFORMATION

5.0 Initial Installation
6.0 Controls
7.0 Inputs and Outputs
8.0 Meter Scales
9.0 Leakage Current and Electrical Hazards
10.0 Bibliography

III. HOSPITAL SAFETY-CHECK PROCEDURE

11.0 Introduction
12.0 Electrical System Wiring Tests
13.0 Appliance Tests

IV. TESTING UNGROUNDED CIRCUITS

14.0 Introduction
15.0 Requirements for Ungrounded Circuits
16.0 Test Procedure

V. PROBLEMS IN TESTING BEDSIDE AND CENTRAL STATION MONITORS

17.0 Introduction
18.0 Test Procedure

CONTENTS (cont'd)

VI. OTHER MICROGUARD USES

19.0 Resistance Measurements
20.0 Current Measurements
21.0 Voltage Measurements
22.0 Leakage Current of 2-Wire Appliances

VII. MAINTENANCE

23.0 Introduction
24.0 To Remove Front Panel
25.0 To Replace Batteries
26.0 To Replace Input Fuse
27.0 To Replace AC Fuse
28.0 Meter Mechanical Zero Adjustment
29.0 Electrical Zero Adjustment
30.0 Calibration

I. GENERAL INFORMATION

1.0 INTRODUCTION

The Bio-Design MICROGUARD is a compact, rugged, easy-to-operate instrument designed for testing the safety and integrity of electronic and electrical equipment and AC power outlets in sensitive areas, such as hospitals, doctors' and dentists' offices, nursing homes, laboratories, assembly lines or any other area where people come in contact with electrical equipment. MICROGUARD is especially valuable in hospitals where patients are often connected to equipment by means of excellent conductors such as ECG electrodes or intravascular catheters. MICROGUARD will test three-wire 115 VAC receptacles for proper wiring. It will measure tiny ground loop voltages or power line voltages. It will check continuity of ground wires, electrodes, chassis connections or cables.

MICROGUARD can also be used as a general purpose instrument to accurately measure AC and DC voltage and current, and resistance. It will indicate voltages as low as 0.5 millivolts and currents as low as 0.5 microampere. The resistance scale is calibrated 0 to 2 ohms.

MICROGUARD is completely portable, using two long-life mercury batteries. Integrated circuits and precision components are used to insure reliability and accuracy. A 3-1/2 inch meter with 3-color dial is featured for easy readability.

2.0 SPECIFICATIONS

2.1 Accuracy: Voltage and current: within ± 3% of full scale on all ranges at DC and 60 Hz.
Ohms: within ± 5% of reading when properly zeroed.

2.2 Frequency Response: DC to 1000 Hz (-3db).
NOTE: The meter will indicate the absolute value of direct current and voltage, regardless of polarity, and the RMS value of a sinusoidal AC waveform.

2.3 Input Impedance:

2000 uA/mV	1000 ohms ± 2%
200 uA/mV	1000 ohms ± 2%
20 uA/mV	1000 ohms ± 2%
200 V	1.0 meg ± 2%
400 V	2.0 meg ± 2%

2.4 Outlet Test: Tests for proper wiring at 115VAC ± 10%.

2.5 Power Supply: Two Mercury batteries, Mallory type TR146X.

2.6 Input Protection: On the current and resistance ranges, the input circuit is protected from damage due to accidental contact with line voltage by means of a fastblow 1 ampere fuse in series with the red test lead. This fuse is accessible from the front panel. As a general rule, avoid connecting the MICROGUARD leads to any voltage source while the selector switch is in the current or resistance positions. Never exceed 400 VDC or RMS at the input.

The MICROGUARD meter is protected by special circuitry and cannot be damaged by input overloads.

2.7 AC Line Cord Protection: The line cord is fused with a 15 ampere fuse, located on the front panel.

Do not plug instruments into the LEAKAGE receptacle whose AC load exceeds 15 amperes.

2.8 Dimensions: 7-15/16 in. (20 cm.) deep,
9-1/16 in. (23 cm.) wide,
4-15/16 in. (12.5 cm.) high.
Handle projects 3/4 in. (1.9 cm) from front surface.

2.9 Weight: 5-1/2 lbs. (2.5 kg.)

3.0 SPECIAL FEATURES

3.1 Test Leads: Two 6-foot test leads, one red and one black, are an integral part of the MICROGUARD and cannot be lost or mislaid. Each lead has a 5-1/4 inch test prod with phone tip.

3.2 Line Cord and Plug: The line cord is heavy-duty, vinyl-covered, 3-conductor type, 5-feet in length. A rugged power plug is used to insure safety and long life.

4.0 ACCESSORIES

4.1 Alligator Clips: Two insulated alligator clips, one red and one black, are included. These fit over the test probe tips.

4.2 Ground Probe: Fits over test probe tip. Ground probe is used for insertion into ground socket of wall outlet.

4.3 Clip Lead: A 10-foot clip lead is provided for convenience in making measurements between remote points.

4.4 Safety-Check Stickers: Fifty Safety-Check Stickers are included with each MICROGUARD to facilitate the periodic inspection and maintenance of equipment and instruments. Record the appropriate information on the Safety-Check Stickers, peel off the backing, and apply the sticker to the tested instrument. Additional stickers may be purchased from Bio-Design, Inc.

4.5 Spare Fuses: Spare fuses are included with each MICROGUARD.

II. OPERATING INFORMATION

5.0 INITIAL INSTALLATION

After opening the shipping carton, inspect the MICRO-GUARD for signs of physical damage. If damage is found, or if the instrument does not meet specifications, notify the carrier and notify Bio-Design, Inc. in writing.

The MICROGUARD is ready for use as soon as it is unpacked and opened. No initial adjustment or calibration is necessary.

6.0 CONTROLS

6.1 Selector Switch: This switch selects the function and range as described below:

OFF: The MICROGUARD is off in this position and there is no battery drain. Always return the switch to this position after use to conserve battery life.

BATT+, BATT-: These two positions check the voltage of the two batteries which power the MICROGUARD. If the meter pointer does not fall in the area marked "BATT OK", replace the batteries immediately. Paragraph 25.0 gives instructions.

OUTLET TEST: This position is used for testing the proper wiring of 115 VAC, 3-wire power outlets.

OHMS: This position is used for checking continuity of ground wires and other conductors and for measuring resistance in the range 0 to 2 ohms.

MICROAMPS/MILLIVOLTS: These ranges are used for measuring AC and/or DC currents from 0.5 microamperes to 2000 microamperes maximum, and also AC or DC voltages from 0.5 millivolts to 2000 millivolts maximum. Since the input resistance of the MICROGUARD is 1000 ohms, either microamperes or millivolts can be read on the same range. This is due to the relationship that microamperes x 1000 ohms = millivolts. The meter indicates the absolute value of direct current and the RMS value of sinusoidal alternating current.

200V, 400V: These ranges are used for measuring AC or DC voltage up to 400 volts.

6.2 Zero/Ohms: This control is adjusted to obtain a meter reading of zero ohms when the Selector Switch is on 0-2 OHMS.

6.3 POWER Switch: This switch applies AC power to the MICROGUARD Test Receptacle and determines the polarity (Normal or Reversed).

6.4 GROUND Switch: This switch, in the CLOSED position, connects the ground socket of the Test Receptacle to the MICROGUARD Chassis ground. In the OPEN position, the Receptacle ground is disconnected from the MICROGUARD chassis ground, allowing ungrounded leakage

current measurements of instruments plugged into the Test Receptacle.
WARNING: DO NOT TOUCH the chassis or exposed metal surfaces of an appliance plugged into the test receptacle when the GROUND switch is OPEN. Under these conditions the appliance safety grounding wire is defeated and a line-to-chassis fault could cause the chassis and exposed metal surfaces to be at line voltage.

6.5 INPUT Switch: This switch selects the MICROGUARD input leads. In the RED PROBE ONLY position, measurements are made with the Red Probe, with reference to the MICROGUARD chassis ground (or electrical system ground when the MICROGUARD line cord is plugged into a wall outlet.) In the RED & BLACK PROBES position, measurements are made with the Red and Black test leads, the MICROGUARD circuit being isolated from chassis ground.

7.0 INPUTS AND OUTPUTS

7.1 Test Probes: Two test probes, one red and one black, are provided for measuring resistance, current and voltage. The probes are connected to the MICROGUARD meter circuit when the INPUT switch is set to RED & BLACK PROBES, and when the selector switch is set to OHMS, 2000, 200, 20, 200V or 400V. When the INPUT switch is set to RED PROBE ONLY, the red probe is still active but the meter circuit is disconnected from the black probe and connected to chassis ground. Both probes are disconnected in the OFF, BATT and OUTLET TEST positions.

7.2 Power Plug: The power plug is used for testing 120 volt AC outlets and for supplying power to the test receptacle. The green wire of the power cord is wired directly to the MICROGUARD panel, grounding the panel when the power plug is connected to a properly grounded outlet.

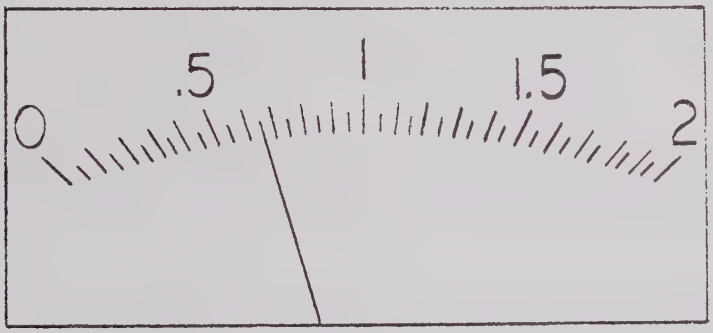
7.3 Test Receptacle: The Test Receptacle provides 120 VAC power to appliances whose leakage current is to be measured. The polarity of the receptacle (normal or reverse) is selected by the MICROGUARD POWER switch, which also turns off the voltage to the receptacle in the OFF position. The receptacle ground socket is wired to the MICROGUARD panel through the GROUND switch. When the GROUND switch is in the OPEN position, the receptacle ground wire is opened, permitting ungrounded leakage measurements. The "Hot" blade of the test receptacle is fused with a 15-ampere fuse. Do not plug in appliances whose load current exceeds 15 amperes.

7.4 Receptacle Ground Tip Jack: The Tip Jack is wired directly to the test receptacle ground socket. It is used for zeroing the OHMS scale, and also provides a convenient method of measuring leakage current of appliances that have no exposed metal or to which access is difficult.

8.0 METER SCALES

8.1 Main Scale: The main scale is calibrated 0 to 2. The full-scale value of the meter is determined by the range to which the selector switch is set. Thus, if the selector switch is set at 2000, a meter reading

of 2 corresponds to actual input of 2000 uA or mV. Likewise, if the selector switch is set at 200V, a reading of 2 corresponds to actual measured voltage of 200 volts. Table 1 gives examples of actual measured values for a typical meter reading.



Range	Meter Reading	Actual Value
2000	.65	650 uA or mV
200	.65	65 uA or mV
20	.65	6.5 uA or mV
200V	.65	65 V
OHMS	.65	.65 ohms

V = volts
uA = microamperes
mV = millivolts

Table 1.

8.2 Ohms Scale: The ohms scale is calibrated 0 to 2 ohms, with the 0 at the left hand end of the scale. If the meter needle points to 2, the measured resistance is 2 Ohms. If the meter needle reads to the right of the 2 mark, the measured resistance is greater than 2 Ohms. Open circuiting the test leads will also cause the meter to read to the right of the 2 mark.

8.3 Outlet Test: Six colored arcs display the condition of 3-wire 115 VAC outlets when the selector switch is on OUTLET TEST. If the meter reads within the green arc marked "OK", the outlet being tested is wired with the proper polarity and the ground connection is intact.

If the meter reads in the red arc marked "NO GND", the outlet ground connection is broken or not wired. In such places as operating rooms, where isolation transformers are used to create an isolated 115 VAC supply, the MICROGUARD will generally indicate "NO GND"; however, the indication may vary from one location to another because of the leakage paths supplied by other equipment or by the transformer and its associated wiring.

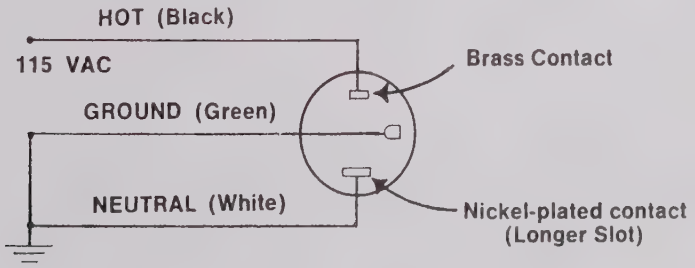
If the meter reads "POL REV", the "Hot" and "Neutral" wires of the outlet under test are reversed, but the ground connection is intact.

If the meter reads "NO NEUT", the neutral terminal of the outlet is broken or unwired.

If the meter reads "HOT GND", the hot wire and the ground wire are interchanged and 115 VAC is present on the ground socket.

CAUTION: This is a rare but dangerous condition as the entire case or chassis of equipment connected to this outlet may be live, including the MICROGUARD panel; therefore, when making outlet tests, do not touch the MICROGUARD panel or any other equipment, until after the MICROGUARD plug has been inserted into the outlet under test, and its condition has been determined.

If an indication of 0 is obtained, there is no voltage to the outlet or the hot terminal is unwired. Use the test leads and the 200V scale to verify. The figure below shows a properly wired outlet.



9.0 LEAKAGE CURRENT AND ELECTRICAL HAZARDS

A hospital electrical safety program should have two primary goals: (1) preventing gross 115 VAC shocks to personnel and patients, resulting from faulty wiring or breakdown of equipment and insulation, and (2) preventing "Micro-shock" due to AC or DC leakage currents finding a path through a patient instead of through secure, low-impedance ground connections.

The major effect of electric shock is ventricular fibrillation, a condition in which the heart does not pump blood, and which if not detected and treated, results in death. 60 hz AC current as low as 20 microamperes passing directly through the heart muscle may cause ventricular fibrillation. This current may result from 100 milliampere currents passing through the arms and legs, or 10 milliampere currents piercing the skin by means of needle electrodes, dye-injectors, blood-pressure transducers, or the like, or it may be applied directly to the heart through such means as pacemaker leads. Whatever the source, the ultimate danger is from the current which passes directly through the heart. While it is beyond the scope of this manual to explore in detail the many complex aspects of electric shock(the operator is referred to the Bibliography found at the end of this section), Figures 1 through 5 show some of the hazardous situations which the MICROGUARD Electrical Safety Tester will detect if used in a regular, systematic preventive maintenance program.

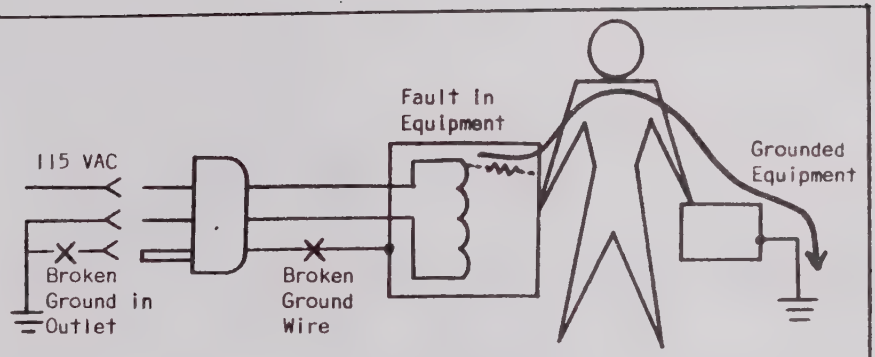


Figure 1. Gross shock due to lack of ground

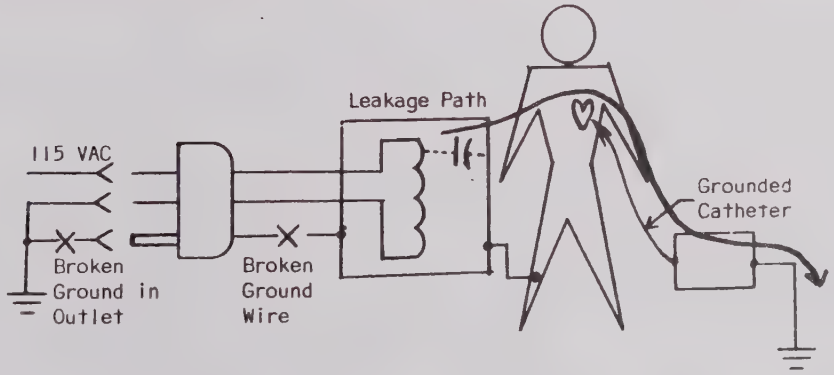


Figure 2. Micro-shock due to lack of ground

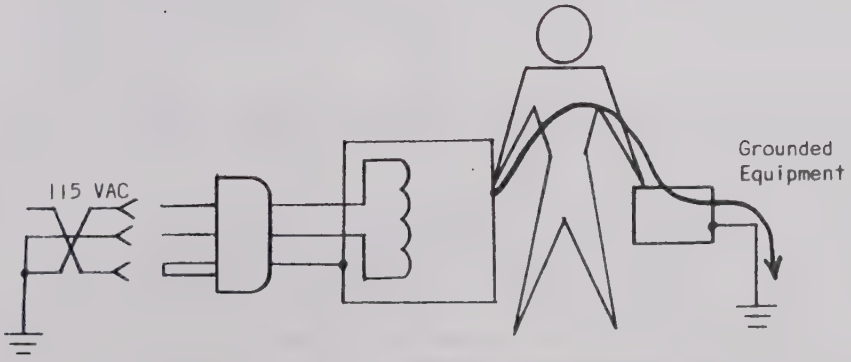


Figure 3. 115 VAC shock due to "hot" ground

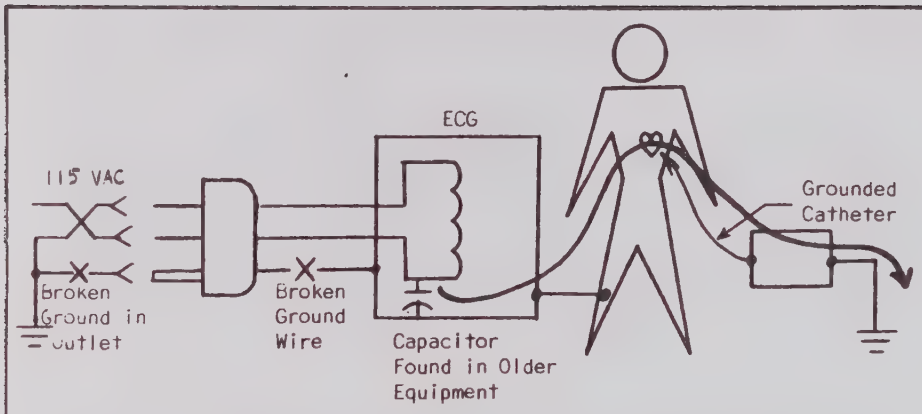


Figure 4. Micro-snock due to reversed polarity

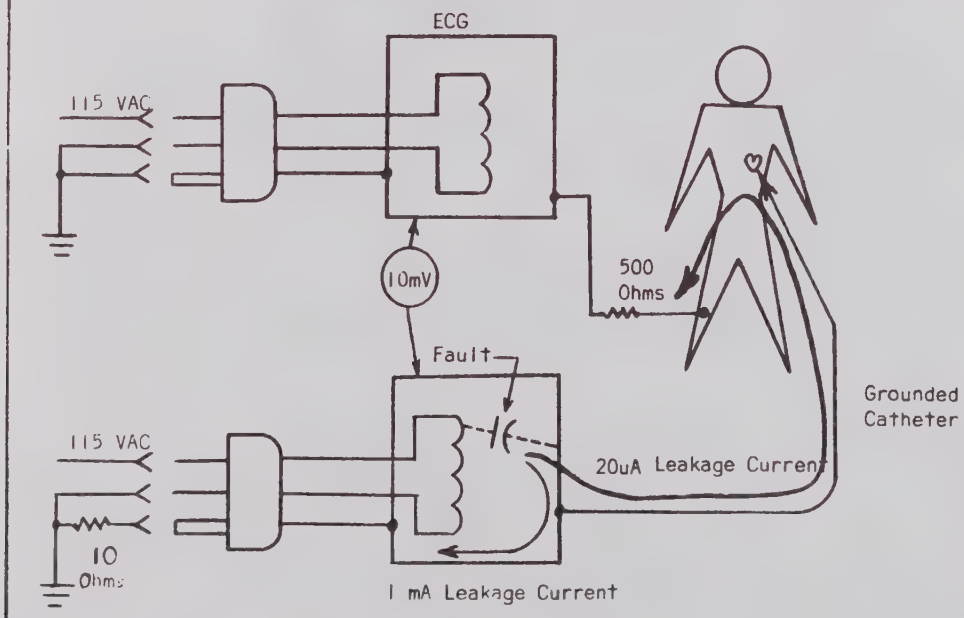


Figure 5. Micro-shock due to ground-loop voltage
(non-equipotential grounds)

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III. HOSPITAL SAFETY-CHECK PROCEDURE

11.0 INTRODUCTION

The MICROGUARD is ideally suited for use in hospitals as an all-purpose safety test instrument. Shock hazards will be greatly reduced through the use of the MICROGUARD in a regular, systematic preventive maintenance program. This program should include all the following steps to insure a safe electrical environment:

(1) Check integrity of AC outlets
(2) Check equipment plugs and grounds
(3) Check cables (Power and Patient) for continuity
(4) Check leakage current of equipment
(5) Check area for equipotential grounds

The use of Bio-Design Safety-Check adhesive labels to identify equipment which has been safety-tested will simplify and expedite your program.

12.0 ELECTRICAL SYSTEM WIRING TESTS

12.1 Battery Check: Always check the MICROGUARD before using to insure accurate performance.

Turn selector switch to BATT+ and BATT-. If in either position the meter does not read in the "BATT" box, change the batteries as instructed in Section 25.0.

12.2 Outlet Test: (Figure 6) Turn selector switch to OUTLET TEST. Insert MICROGUARD plug into all 3-wire 120 VAC receptacles in the area. If any reading other than "OK" is obtained, immediate action should be taken to correct the existing condition. Record results on suitable data sheet, such as a Bio-Design Outlet Inspection Card.

CAUTION: The "HOT GND" condition is a rare but dangerous condition in that the entire case or chassis of equipment connected to this outlet may be live, including the MICROGUARD panel; therefore, when making outlet tests, do not touch the MICRO-GUARD panel, or any other equipment until after the MICROGUARD plug has been inserted into the outlet under test, and its condition has been determined.

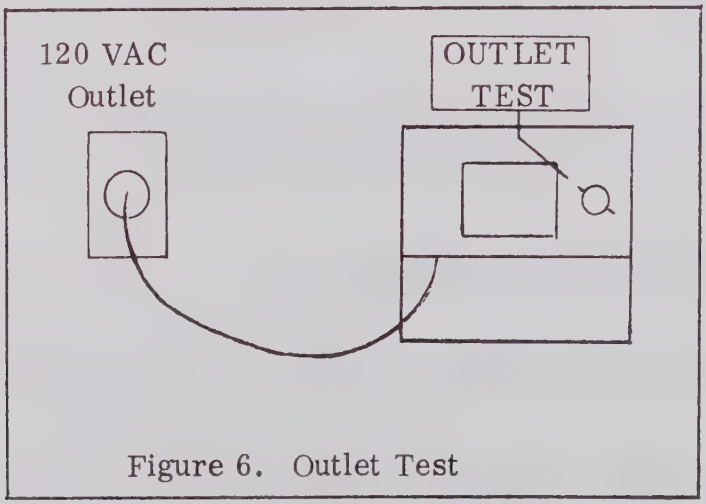

Figure 6. Outlet Test

12.3 Voltage Differences Between Outlet Grounds or Conductive Surfaces.

Perform this test in sensitive areas periodically or prior to connecting electrical instruments to a patient.

1) Plug MICROGUARD line cord into wall outlet.

2) Set INPUT switch to RED PROBE ONLY.

3) Set Selector switch to 20uA/mV.

4) Insert Red Test Probe into ground socket of all other AC outlets in the area. If the voltage measured is larger than 5 millivolts, the area grounds possess a voltage difference which may be a source of leakage current to patients. If this is the case, the use of an "equalizing ground bus" is recommended. (Contact Bio-Design, Inc. for further details)

5) Record results on suitable data sheet, such as Bio-Design Outlet Inspection Card.

Alternate Method for outlets spaced more than ten feet apart. (Figure 7)

6) Disconnect MICROGUARD plug from AC outlet.

7) Set INPUT switch to RED & BLACK PROBES.

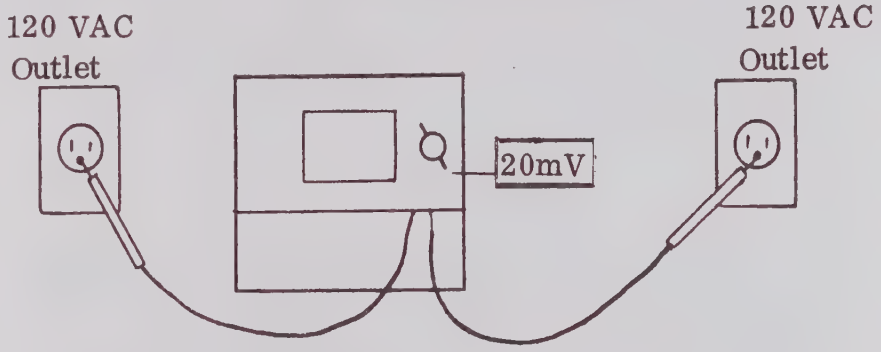

Figure 7. Voltage Difference Between Grounds

8) Set Selector switch to 20uA/mV.

9) Connect black probe to ground socket of wall outlet using 10-foot clip lead and ground probe provided with MICROGUARD.

10) Insert red test probe into ground socket of other outlets and record results as in steps (4) and (5)

12.4 Outlet Ground Resistance Test: (Figure 8)
Check outlet grounds to insure that they are low resistance.

1) Disconnect MICROGUARD plug from AC outlet.

2) Turn the selector switch to OHMS, INPUT switch to RED & BLACK PROBES.

3) Zero the ohms scale: short the red and black test leads together and adjust the ZERO OHMS control for a meter reading of 0 ohms.

4) Connect one test lead of the MICROGUARD to a convenient, certain ground, such as patient ground bus if there is one, or cold water pipe.

5) Connect the other test lead to the ground socket of the outlet under test. The meter should indicate less than .1 ohm or whatever present standards allow. A reading of several ohms or higher indicates an inadequate ground which should be repaired.

6) Record results on Outlet Inspection Card.

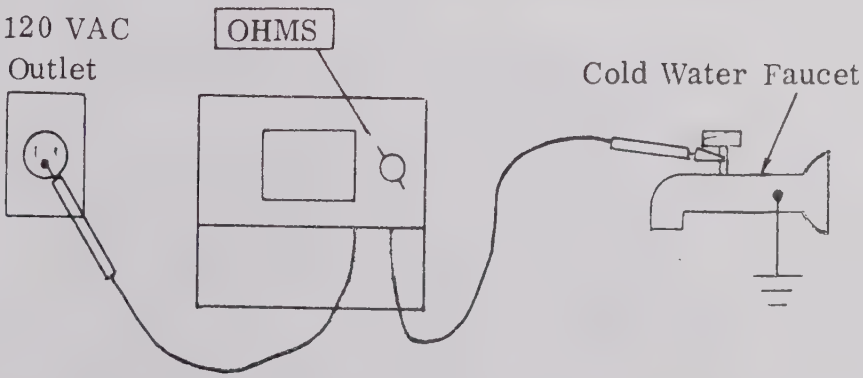

Figure 8. Outlet Ground Resistance Test

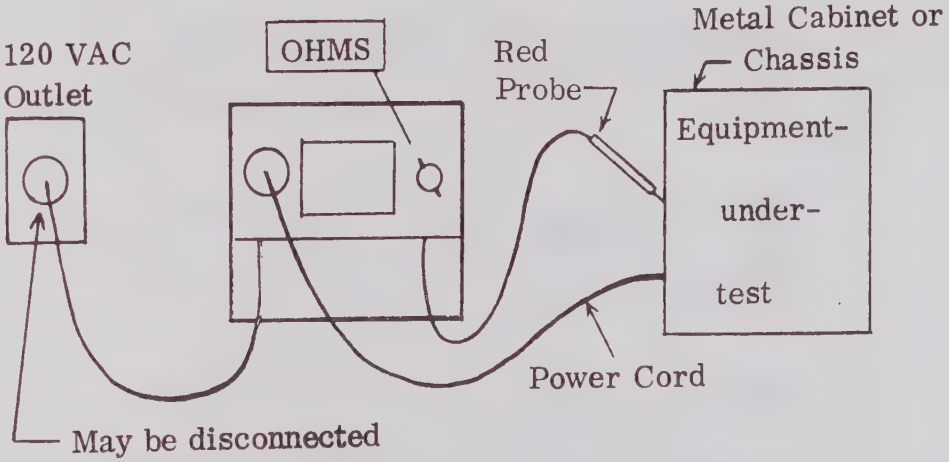

Figure 9. Grounding Wire Continuity

3.0 APPLIANCE TESTS

13.1 Continuity of Grounding Wire in 3-Prong Power Plugs: (Figure 9)

1) Set Selector switch to OHMS.
2) Set INPUT switch to RED PROBE ONLY, POWER switch to OFF.
3) Plug Red Probe into Receptacle Ground Tip Jack, and slowly adjust ZERO OHMS control until meter needle rests as far to the left as possible. (Over-adjustment will cause the needle to move back to the right.)
4) Insert the power plug of appliance-under-test into the MICROGUARD receptacle.
5) Connect the Red Probe to an exposed metal part of the chassis of the equipment-under-test. The meter should indicate less than 0.5 ohms or whatever present standards allow. If high resistance is indicated, a

faulty plug or broken wire is present and should be repaired. If the ground wire is satisfactory, place a check mark in the appropriate box on a Bio-Design Safety-Check Sticker, and record readings on Patient Monitor Inspection Card or General Equipment Inspection Card.

6) Alternate method: Set INPUT switch to RED & BLACK PROBES, short red and black probes together and adjust ZERO OHMS control. Connect one test lead to the chassis of the appliance-under-test. Connect the other test lead to the power plug ground prong of the appliance power plug and observe the meter indication. Record results as in (5) above.

13.2 Leakage Current of Electrical Appliances and Equipment (See Figure 10)

1) Set INPUT switch to RED PROBE ONLY.
2) Set Selector switch to 2000 uA/mV.
3) Plug MICROGUARD line cord into properly tested 120 VAC outlet.
4) Plug line cord of appliance-under-test into MICROGUARD receptacle.
5) Set MICROGUARD POWER switch to NORM.
6) Apply Red probe to exposed metal surfaces of appliance.
7) If there is no meter reading, turn selector to 200 or 20 until reading is obtained. This reading is "grounded" leakage current.
8) Hold GROUND switch OPEN to read "ungrounded" leakage current. Select appropriate range.

WARNING: DO NOT TOUCH the chassis or exposed metal surfaces of an appliance plugged into the MICROGUARD receptacle when the GROUND switch is OPEN. Under these conditions, a line-to-chassis fault in the appliance could cause its chassis and exposed metal surfaces to be at line voltage, 120 VAC.

9) Leakage current should be measured under the following conditions:
   a) POWER switch NORM, appliance power "off", GROUND switch CLOSED and OPEN.
   b) POWER switch NORM, appliance power "on", GROUND switch CLOSED and OPEN.
   c) POWER switch REV, appliance power "off", GROUND switch CLOSED and OPEN.
   d) POWER switch REV, appliance power "on", GROUND switch CLOSED and OPEN.

10) Record results on suitable data sheet or on a Bio-Design General Equipment or Patient Monitor Inspection Card.

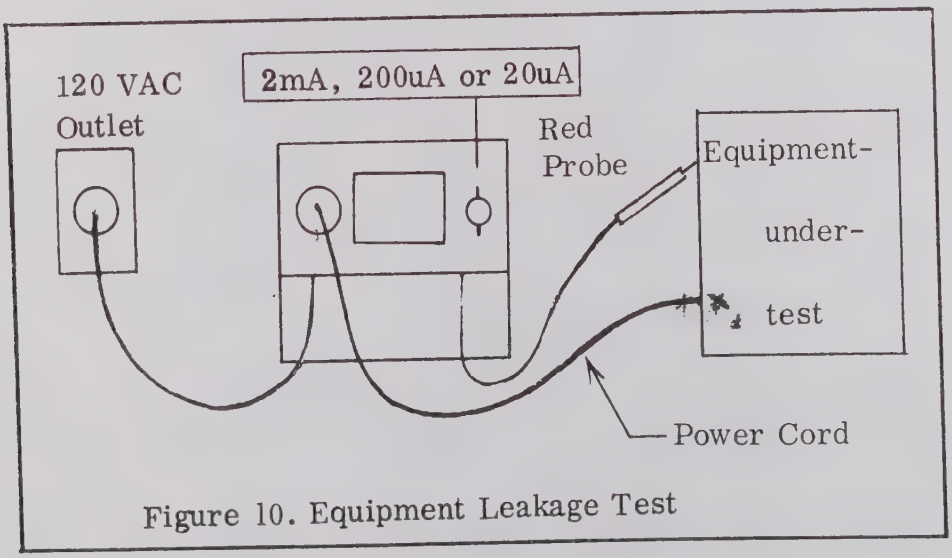

Figure 10. Equipment Leakage Test

11) Record the highest reading obtained on a Bio-Design Safety-Check Sticker and affix to appliance.

CAUTION: Be sure that the appliance-under-test is not grounded by means other than the line cord or readings will be incorrect. Other means may include metal brackets, metal shelves, signal cables, etc. (See Section 17.0)

13.3 Leakage Current-Alternate Method

Use the following method for appliances which have no exposed metal surfaces or appliances to which access is difficult.

1) Repeat steps (1) through (5) of section 13.2.

2) Plug Red Probe into Receptacle Ground Tip Jack on MICROGUARD panel.

3) Measure and record leakage current as steps (7) through (11) of section 13.2.

13.4 Leakage Current of Patient Leads Using the Bio-Design Lead Test Adapter, Model ALT-5

Instruments which have leads connecting directly to the patient such as patient monitors, ECG, EEG, apnea or respiration monitors, etc. may be tested for patient lead leakage current by using the MICROGUARD in conjunction with the Bio-Design model ALT-5 Patient Lead Test Adapter. Complete instructions are given in the ALT-5 Instruction Manual.

13.5 Leakage Current of Patient Leads Using the MICROGUARD Alone

1) Plug MICROGUARD line cord into properly tested 120 VAC outlet.

2) Plug instrument-under-test into MICRO-GUARD test receptacle.

3) Set POWER switch to NORM, INPUT switch to RED PROBE ONLY.

4) Set Selector Switch to 2000 uA/mV.

5) Connect Red Probe to patient lead to be measured (e.g. R A)

6) Hold GROUND switch "OPEN", select appro-priate range, and read leakage current.

7) NOTE: If instrument-under-test is an electrocardiograph, rotate lead selector switch until maximum reading is obtained. Do not leave in "standard" or inactive position.

8) Repeat leakage current measurement for each lead under following conditions: Instrument Power on, polarity NORM and REV, Instrument Power off, polarity NORM and REV.

9) Record results on suitable data sheet, or on Bio-Design Patient Monitor Inspection Record Card.

Leakage Between Leads

10) Set INPUT switch to RED & BLACK PROBES.

11) Connect Red Probe to RA, Black Probe to LA, hold GROUND switch OPEN and measure leakage current.

12) Measure leakage with instrument power on, polarity NORM and REV, instrument power off, polarity NORM and REV.

13) Record results on Patient Monitor Inspection Record Card.

14) Repeat steps (11) through (13) for RA to RL, and RL to LA.

Leakage Current of Isolated Patient Leads
Instruments with isolated patient leads are tested by applying 120 VAC to each lead in series with an AC microammeter such as the MICROGUARD. For operator safety reasons it is recommended that this test be performed with a suitable adapter such as the Bio-Design Model ALT-5 Test Adapter.

13.6 Leakage Current Between Equipment: (Figure 11)
Perform this test immediately before connecting electrically-operated devices to patients, especially before catheterization, internal pacing, or any other procedure which violates the skin.

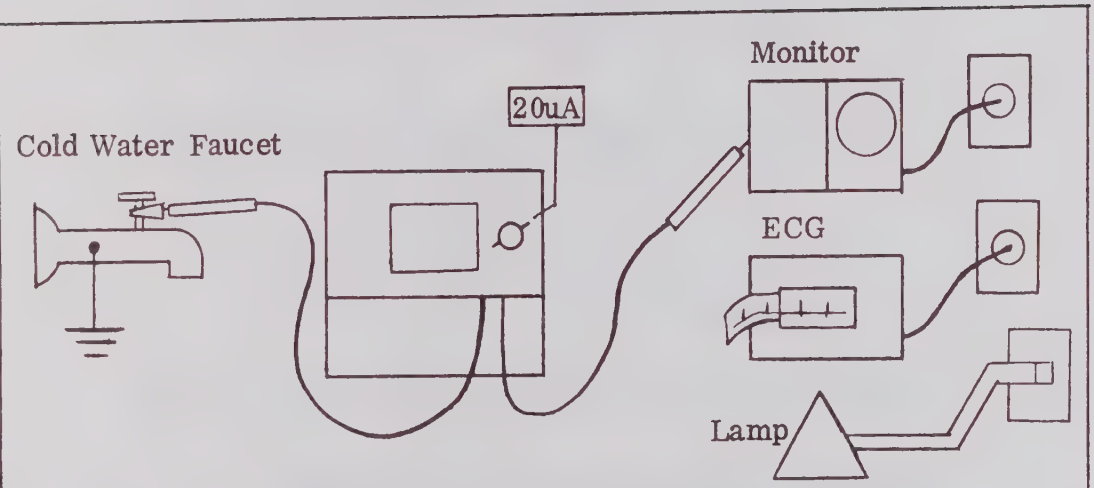

Figure 11. Leakage Current Between Equipment

1) Disconnect MICROGUARD Plug from AC outlet.
2) Turn selector switch to 20 uA, INPUT switch to RED & BLACK PROBES.
3) Connect one test lead to an established electrical ground, such as a patient ground bus, cold-water pipe, or properly grounded AC outlet.
4) With the other test lead, touch exposed metal surface of all other electrically-operated equipment in the area. Also apply to patient electrodes. Typical appliances which should be checked include:

Electrocardiographs
Electroencephalographs
Cardiac Monitors
Physiological Monitors
Blood Pressure Transducers
Respiration Monitors
Intravascular Catheters
Bovie or Electrosurgery Machines
Anesthesia Masks
Suction Pumps
Inhalators
Respirators
Televisions
Radios, AC operated
Electric Beds
Any electrical device which a patient may intentionally or accidently touch

5) All readings should be less than 10 uA, or whatever present standards allow. If the MICROGUARD meter indicates excessive leakage between any of the above objects, a hazardous situation exists, which requires the removal or replacement of equipment or the use of an equalizing ground bus or isolation transformer.

13.7 Discussion of Leakage Current:
If "excessive" leakage current is measured in any of the previous tests, the appliance may be unsafe for use in the intended area or may have an electrical fault and be in need of immediate repair. See Section 13.8 for discussion of Limits.

A significant increase in leakage current between two successive readings indicates an impending or existing fault in the equipment-under-test.

If reading of less than 3 or 4 uA is obtained for "ungrounded" leakage current, repeat the test for appliance grounding wire resistance (Sec.13.1) to see that the grounding wire is not broken. if it tests OK, check the AC outlet for proper wiring (Sec. 12.2). If the outlet tests OK, refer to Section 17.0 for possible measurement problems that occur when testing patient monitors.

13.8 Leakage Current Limits:
For the latest standard on leakage current limits, the user should refer to the following documents:

A. Tentative Standard 76B-T - National Fire Protection Association, Boston, Mass. 02210

B. Standard for Medical and Dental Equipment-544 - Underwriters' Laboratories, Melville, N. Y. 11746

C. Safe Current Limits - Association for the Advancement of Medical Instrumentation, Arlington, Va. 22209

Leakage current limits for ungrounded appliances as stated in NFPA 76B-T are summarized below:

Appliances Not in Contact with Patient	500 uA
Appliances Likely to Contact Patient	
Chassis	100 uA
Patient Leads	50 uA
Appliances with Isolated Patient Leads	
Chassis	100 uA
Patient Leads	10 uA

IV. TESTING UNGROUNDED CIRCUITS

14.0 INTRODUCTION

The Bio-Design MICROGUARD® Safety Tester can be used for making quick and convenient checks of "ungrounded" or "isolated" 120 VAC circuits, such as those found in hospital operating rooms. First, a discussion of isolated circuits is in order.

Isolated circuits, that is AC circuits which are fed from isolation transformers, are required in all operating rooms because they offer the following benefits:

14.1 No arc or spark hazard from accidental grounding of the line. Accidental grounding of a normal circuit produces an arc which could be extremely dangerous in the presence of oxygen and explosive anesthetics. In an isolated circuit, grounding either side of the line causes that side to become ground and the other side to become the "hot" side. Thus, the danger of arcing is virtually eliminated.

14.2 Elimination of Shock Hazard

Operating rooms have conductive floors and doctors and nurses wear conductive boots in order to minimize sparking due to build-up of static electricity. Because the personnel are so well grounded, the danger of shock from accidental contact with line voltage is greatly increased. An isolated system reduces the shock hazard because the side which is contacted instantly becomes"ground".

14.3 Reduction of AC Leakage Current

Another advantage of isolated circuits is the considerable reduction of 60 hz AC leakage current in equipment ground wires. In Fig. 12, a conventional grounded circuit, Point A, is at line potential and leakage current flows through the stray capacitance to the chassis and back through the ground wire. In Figure 13, an isolated circuit, current can flow from the "hot" side through the primary-to-secondary capacitance of the isolation transformer, through Point A to the chassis. The primary-to-secondary capacitance of the transformer is usually much smaller than the capacitance from Point A to chassis; therefore, very little leakage current will flow in the equipment ground wire.

Low leakage current is important in catheterization, pace-making or other procedures in which the patient's skin is violated.

15.0 REQUIREMENTS FOR UNGROUNDED CIRCUITS

The National Fire Protection Association's Code for the use of Inhalation Anesthetics (NFPA 56 A) requires that each ungrounded system be provided with a ground fault indicator that signals when the fault resistance or capacitive reactance from either conductor to ground is less than 60,000 ohms, which would result in fault current exceeding 2 milliamperes.

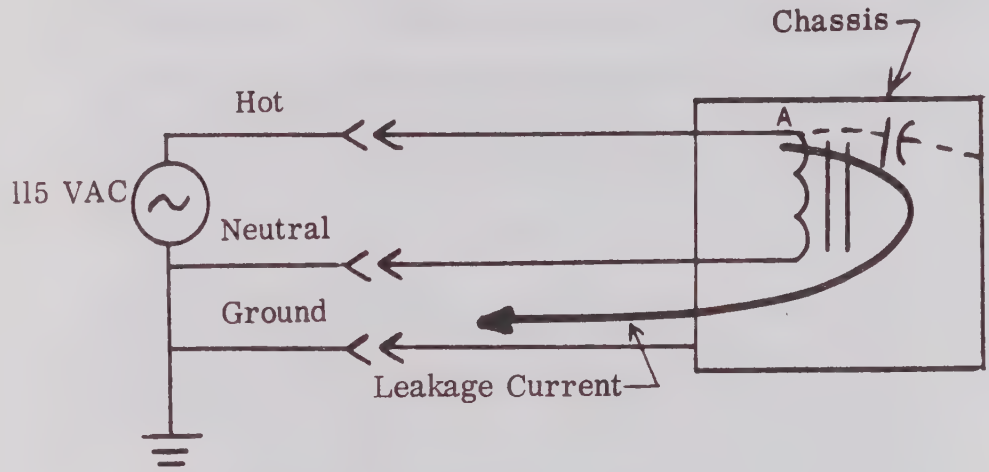

Figure 12. Leakage Current in grounded system

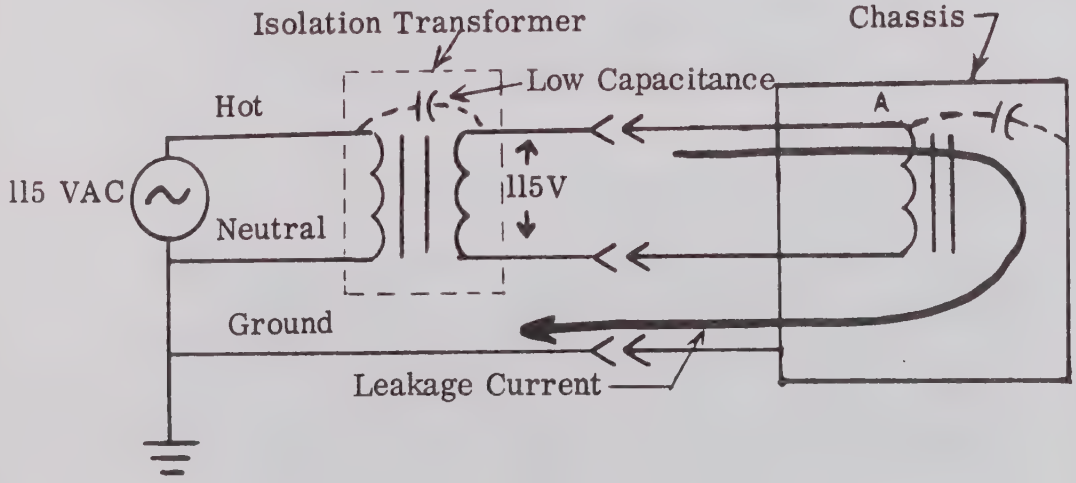

Figure 13. How Isolation reduces leakage current

Whatever the limit, it is desirable to measure the actual hazard current present periodically to assure that the ground fault indicator is operating properly. The MICROGUARD will measure these currents when used as indicated below.

16.0 TEST PROCEDURE

1) Disconnect MICROGUARD power plug from AC outlet.
2) Set MICROGUARD selector switch to 2000 uA, INPUT switch to RED & BLACK PROBES.
3) Connect the black test lead to a known reference ground.
4) Connect the red test lead to one side of the ungrounded circuit and note reading. An adapter will be necessary if locking type receptacles are used on the isolated circuit.
5) Connect the red test lead to the other side of the ungrounded circuit and note reading. The highest of the two readings represents the maximum fault current which will flow if one side of the ungrounded circuit becomes grounded.

NOTE: The line isolation monitor alarm should go on when the MICROGUARD is connected from one side of the isolated circuit to ground. This is normal, and indicates the alarm circuit is working properly.

V. PROBLEMS IN TESTING BEDSIDE AND CENTRAL STATION MONITORS

17.0 INTRODUCTION

Unusual readings frequently arise when measuring leakage current of bedside and central station monitors with the MICROGUARD Safety Tester. For example:

1) Zero leakage current.
2) The meter pulsates at a rate identical, strangely enough, to the heart rate of the patient being monitored.

These symptoms arise in patient monitoring systems where the bedside and remote monitor are connected by a signal cable in which the shield or separate ground wire is carried through. This creates a troublesome "ground loop", as the diagrams illustrate.

Figure 14 shows the leakage current of the instrument-under-test being shorted to ground by means of the bedside-to-remote signal cable, thus the meter reads 0 leakage current. We know that zero leakage is impossible, because we should at least measure the leakage current of the monitor line cord, typically 1 to 2 microamperes per foot.

Figure 15 shows why the MICROGUARD meter will sometimes pulsate at the patient's heart rate. The patient's ECG signal current is transmitted from the bedside amplifier over the signal wire to the central station monitors. Since electrical circuits must have a continuous path, the ECG signal current returns through a ground wire or through the cable shield;

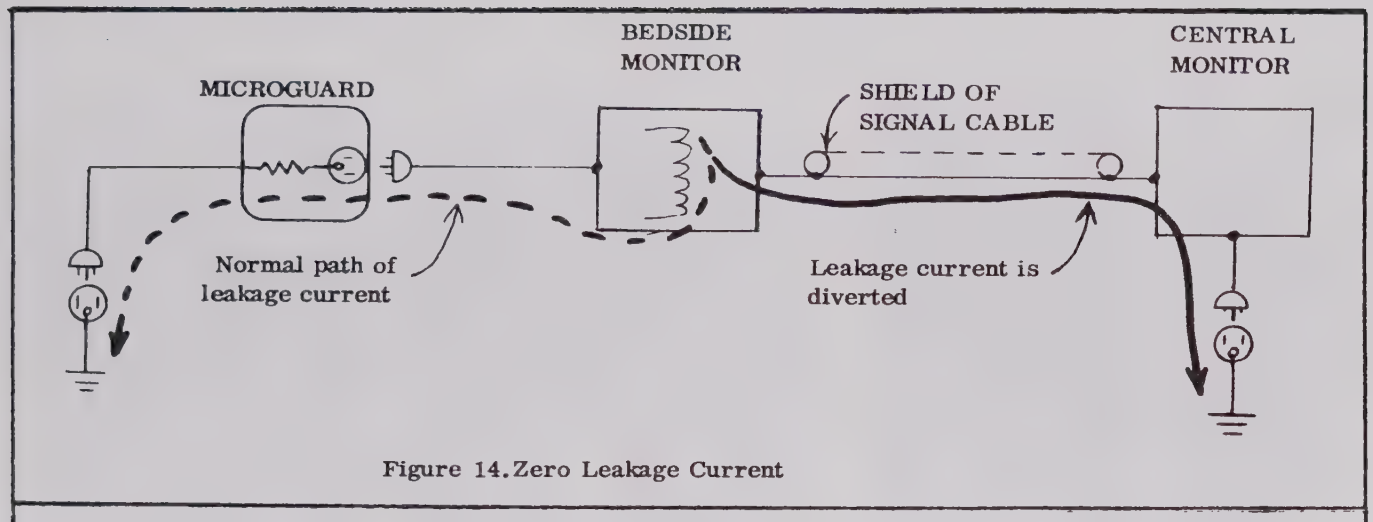

Figure 14. Zero Leakage Current

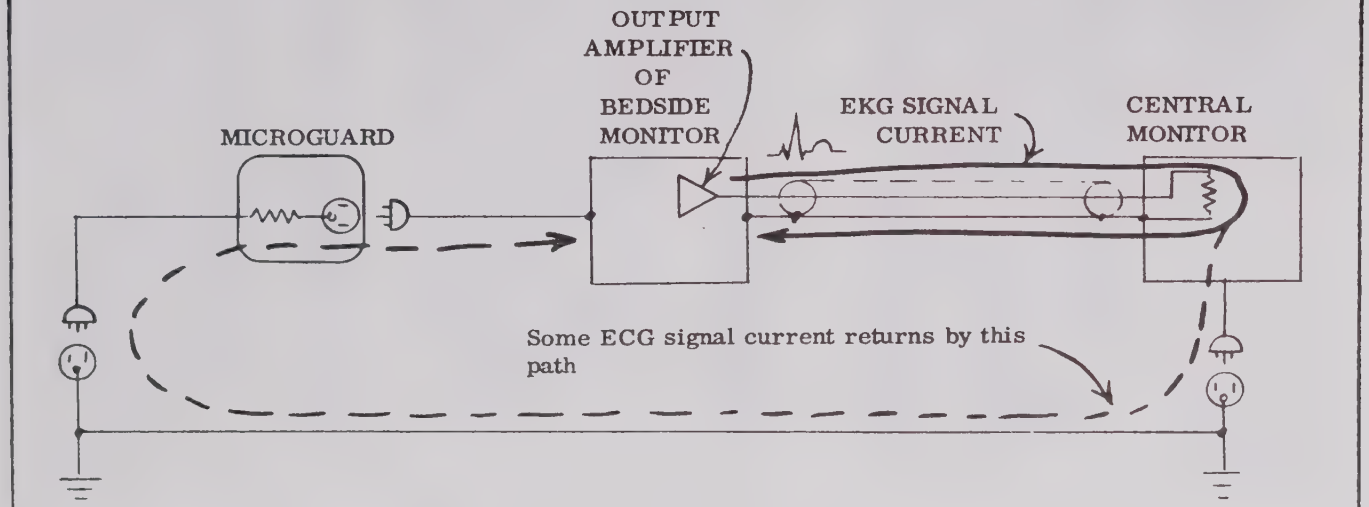

Figure 15. Pulsating Meter

however, some of the signal current may flow through an alternative path to return to the bedside amplifier, (in this case through the MICROGUARD) thus causing the meter to pulsate.

In some of the newer monitoring systems, this condition is eliminated because the manufacturers use "differential" output amplifiers, which "float" the signal above ground, and do not require the ground wire as a return path for the signal current. It is definitely advisable to have the cable shield grounded only at one point, either at the bedside monitor, or the remote monitor.

18.0 TEST PROCEDURE

18.1 Before measuring leakage current of bedside monitors, disconnect the output signal cable from the bedside monitor. (The output signal cable is usually located at the back of the bedside monitor and connects to a special wall receptacle. It is sometimes labeled "To Remote".) This eliminates the troublesome ground loop and results in accurate leakage current readings.

Be sure to inform the ICU nurse that you are disconnecting the signal to the central monitor.

18.2 Measure leakage current using the procedure of Section III, paragraph 13.2.

VI. OTHER MICROGUARD USES

19.0 RESISTANCE MEASUREMENTS (0 to 2 ohms)

1) Disconnect MICROGUARD plug from AC outlet.
2) Turn selector switch to OHMS, INPUT switch to RED & BLACK PROBES.
3) Short the red and black test leads together and adjust the ZERO OHMS Control for a meter reading of 0 ohms.
4) Connect the test leads to the unknown resistor and read the resistance on the ohms scale of the meter.

CAUTION: Do not make resistance measurements in a circuit in which live voltages are present, or erroneous readings will result.

20.0 CURRENT MEASUREMENTS

The MICROGUARD may be used as a sensitive AC or DC microammeter. It will indicate the absolute value of direct current, regardless of polarity, and the RMS value of alternating current.

1) Disconnect MICROGUARD power plug from AC outlet.
2) Turn selector switch to 2000 uA, INPUT switch to Red and Black probes.
3) Turn off power to the circuit under test.
4) Connect test leads so that MICROGUARD is in series with the circuit under test.
5) Turn on power to the circuit under test and select appropriate current range 2000uA, 200uA, or 20uA).

21.0 VOLTAGE MEASUREMENTS

The MICROGUARD may be used as an AC or DC voltmeter. It will indicate the absolute value of a DC voltage, regardless of polarity, and the RMS value of an AC voltage.

1) Disconnect MICROGUARD power plug from AC outlet.
2) Turn selector switch to appropriate voltage range (200V, 400V, 2000mV, 200mV, or 20mV). Turn INPUT switch to RED and BLACK PROBES.
3) Connect the test leads to the voltage source to be measured.

CAUTION: Do not touch the metal parts of the test probes while making voltage measurements as they may be exposed to live voltage.

22.0 LEAKAGE CURRENT OF 2-WIRE APPLIANCES (in conformance with A.N.S.I. Standard.

1) Turn selector switch to 2000uA. INPUT switch to RED PROBE only, POWER switch to NORM.
2) Plug appliance into MICROGUARD receptacle.
3) Plug MICROGUARD power plug into 3-wire, 120 VAC outlet.
4) Connect red test lead of MICROGUARD to all exposed conductive surfaces of appliance, and note maximum meter reading.
5) Set POWER switch to REV.
6) Again, connect red test lead to all exposed conductive surfaces of the appliance, and note maximum meter reading.
7) Readings should not exceed 500uA in either case.

VII. MAINTENANCE

23.0 INTRODUCTION

The Bio-Design MICROGUARD is designed to give long and reliable operation with a minimum of maintenance. Periodically, it will be necessary to change batteries. Follow the procedure given below. Occasionally, the front panel should be removed and the inside of the instrument cleaned of accumulated dust and grit. Instructions are also given below for the meter zero adjustment and circuit zero adjustment. These procedures may be necessary after batteries are replaced.

24.0 TO REMOVE FRONT PANEL

1) Be sure MICROGUARD power plug is disconnected from AC outlet and selector switch is turned off.
2) Remove the four (4) screws located at the corners of the front panel.
3) Lift the panel straight up, grasping the selector knob and the left hand fuse holder. Do not grasp the meter.

25.0 TO REPLACE BATTERIES

1) Remove panel as instructed above.
2) Place panel face down on paper or cloth to avoid scratching meter face.
3) With batteries toward you (see Figure 16), replace righthand battery if BATT+ reads low. Replace lefthand battery if BATT- reads low. Replace with Mallory type TR146X battery or equivalent. These may be ordered from Bio-Design, Inc. or may be purchased at a local distributor.

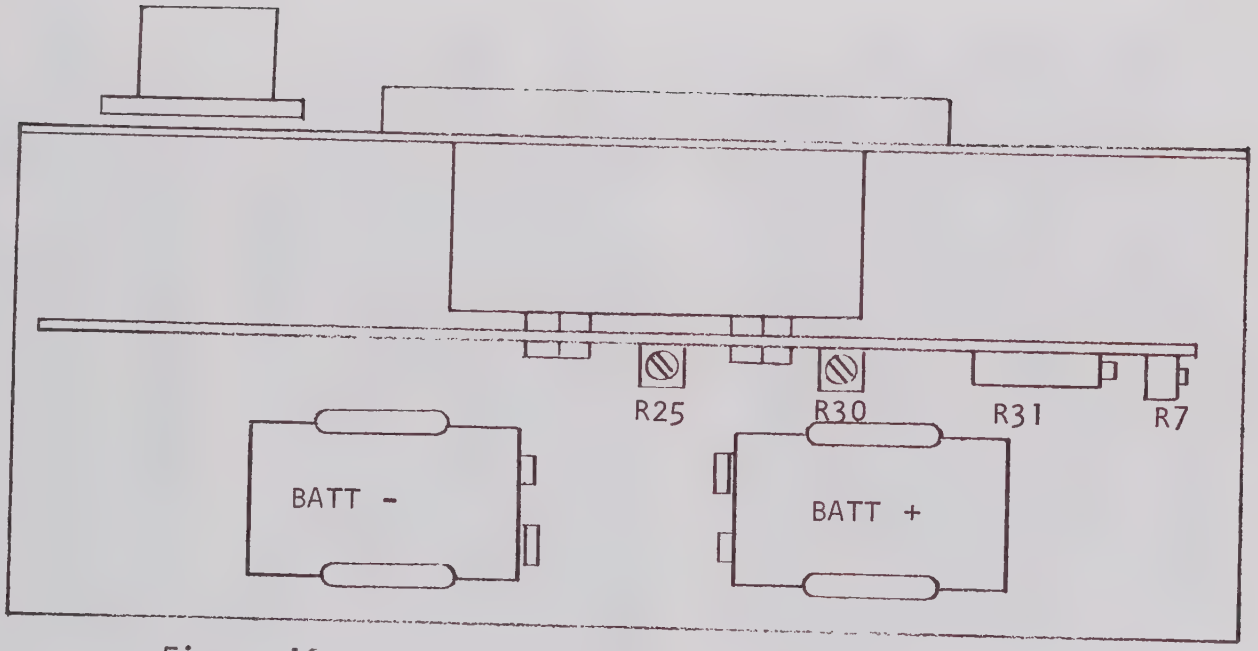

Figure 16. Battery and potentiometer locations.

26.0 TO REPLACE INPUT FUSE

1) To test input fuse, set INPUT switch to RED and BLACK PROBES, turn selector switch to OHMS and short test leads together. If pointer does not move, input fuse is most likely blown.
2) Disconnect MICROGUARD plug from AC outlet.
3) Twist cap of fuseholder 1/4 turn counterclockwise and pull out.
4) Replace fuse, push cap in and twist 1/4 turn clockwise. Use 1 ampere fuse, type 3AG or AGC.

27.0 TO REPLACE AC FUSE

1) Disconnect MICROGUARD plug from AC outlet.
2) Twist cap of fuseholder 1/4 turn counterclockwise and pull out.
3) Replace fuse, push cap in and twist 1/4 turn clockwise. Use 15 ampere fuse, type 3AB or ABC

28.0 METER MECHANICAL ZERO ADJUSTMENT

1) Place the MICROGUARD so that the meter is horizontal, face up.
2) Turn the selector switch to OFF.
3) If the pointer is off zero, slowly adjust the small black screw below the meter face with a small screwdriver, until the pointer is exactly over the zero mark at the left side of the scale.

29.0 ELECTRICAL ZERO ADJUSTMENT

1) Remove the panel as instructed in paragraph 2.0 and place so that meter is horizontal, face up.
2) Turn the selector switch to 2000 uA/mV.
3) Locate R31, a rectangular potentiometer behind the leakage receptacle. (See Figure 16)
4) With a small screwdriver, slowly adjust R31 so that the pointer rests as far to the left as possible. Over-adjustment will cause the pointer to move back to the right.

30.0 CALIBRATION

It is desirable to calibrate the instrument periodically or as a performance check after severe handling or electrical overload. Follow the procedure given below.

30.1 Test Equipment Required

1) Power supply, 0 to 20 volts DC.
2) Voltmeter, DC, digital ± 0.1% accuracy or better.
3) Voltmeter, AC, ± .5% accuracy or better at 60 Hz.
4) Resistor, precision 1.0 Megohm, ±1%, 1/2W, type RN65D or equivalent.
5) Resistor, precision, 2.0 ohms ±1%, wirewound.
6) Variable Autotransformer, 0 - 120 VAC, 60Hz.

30.2 Perform zero adjustment procedures of sections 28.0 and 29.0.

30.3 DC Calibration

1) Remove MICROGUARD panel from case, as instructed in paragraph 24.0 and place so that the meter is horizontal, face up.
2) Connect test equipment as shown in Figure 17.
3) Set DC power supply to 20.0V DC.
4) Set MICROGUARD selector switch to 20uA range. Set INPUT switch to RED and BLACK PROBES.
5) Adjust R30 with a small screwdriver so that MICROGUARD meter reads 20.0uA.

30.4 AC CALIBRATION (Always perform 30.3 first)

1) Set MICROGUARD selector switch to 20uA range. Set INPUT switch to RED and BLACK PROBES.
2) Connect test equipment as shown in Figure 18.
3) Adjust Variable Transformer for a reading of 20.0VAC on AC Voltmeter.
4) Adjust R25 until MICROGUARD meter reads 20.0uA.

30.5 OHMS Calibration

1) Equipment required: 1. Digital voltmeter
   2. Resistor, 2.0 ohms, ± 1%
2) Perform zero adjustment procedure of Section VII, paragraphs 28.0 and 29.0.
3) Set Selector Switch to OHMS, INPUT switch to RED and BLACK PROBES.
4) Connect 2.0 ohm, 1%, resistor across Microguard test leads. Simultaneously connect digital voltmeter leads across 2.0 ohm resistor.

5) Adjust 500-ohm potentiometer R7 on circuit card until digital voltmeter reads 20.0 millivolts DC.
6) Short test leads together and adjust ZERO OHMS control for meter reading of 0 ohms. Remove short.
7) Connect 2.0 ohm resistor across Microguard test leads. Meter should indicate 2.0 ± .1 ohms.

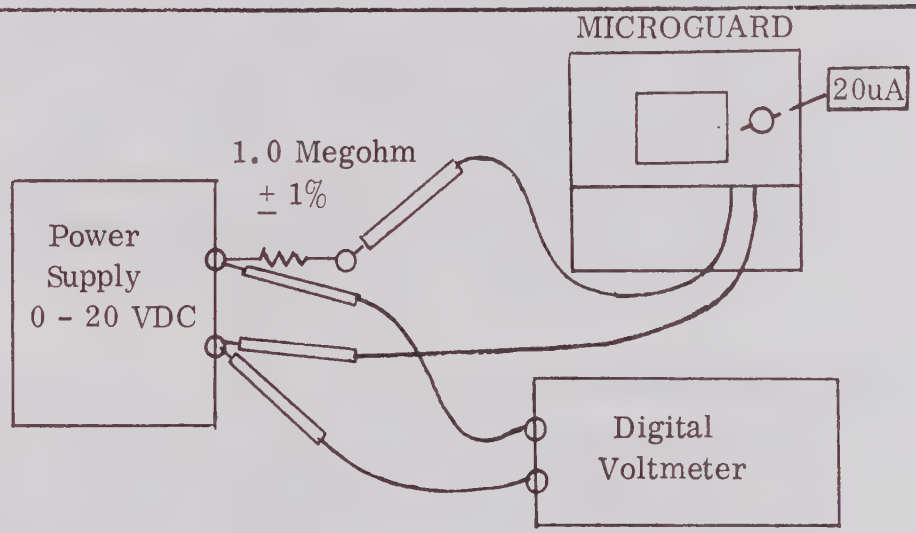

Figure 17. DC Current Calibration Setup

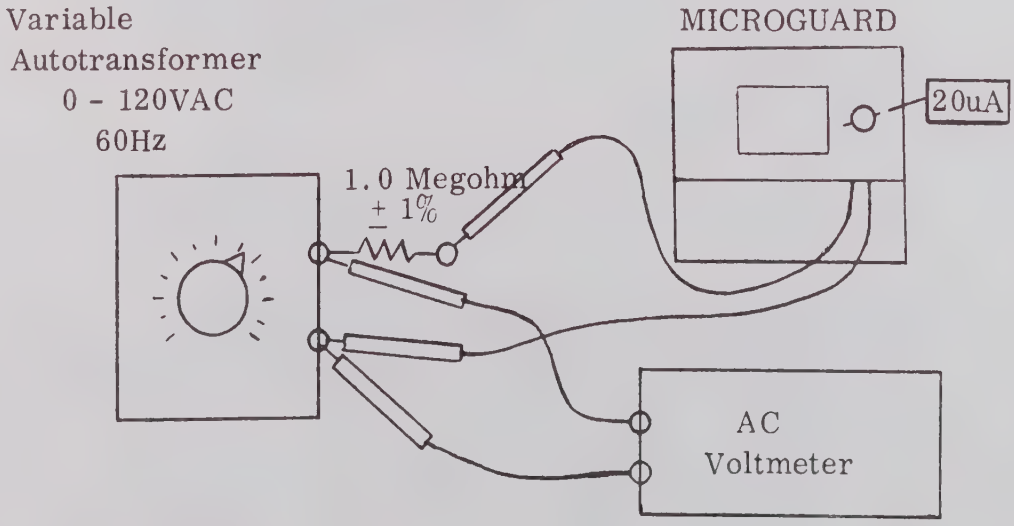

Figure 18. AC Voltage Calibration Setup

MP MASTER
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